Remarks

The 35 U.S.C. 112, first Paragraph Rejection

Claims 3 and 5-12 have been rejected as allegedly unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabled for the prevention of breast cancer using the compound lasofoxifene. The Examiner, in the office action dated December 11, 2008, the final office action of March 30, 2009, and in the non-final office action of September 1, 2009 has alleged that "the instant specification does not make it clear that the prevention of breast cancer means to reduce the incidence of breast cancer" and "the specification does not appear to define the scope of preventing breast cancer." The Examiner has also alleged that undue experimentation would be required to practice the claimed invention. The Examiner goes on to say that "the crust (sic) of the argument surrounds the term prevent(ing) and its interpretation. The Examiner argues that while it is true that the references provided by Applicants state that reducing the incidence of breast cancer means to prevent breast cancer, the instant original specification does not define the term "prevention" and its scope/breath (sic) to include the reduction of the incidence of breast cancer. The foundation of the rejection stand on this fact."

Applicants respectfully traverse this rejection. Applicants submit that the crux of the rejection is the interpretation of the term "prevention." When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must read as they would be interpreted by those of ordinary skill in the art. *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed Cir. 1983), see also MPEP 2111.

Applicants maintain that the claimed prevention of breast cancer with lasofoxifene is a credible utility that is clear, definite and understood by one skilled in the art in view of the specification when the terms in the claims are given their plain meaning. Applicants further submit that one skilled in the art understands that the reduction in incidence of breast cancer achieved with lasofoxifene is prevention of breast cancer through use of lasofoxifene.

The Examiner previously admitted that lasofoxifene has been revealed to prevent breast cancer as evidenced by reducing the risk of or incidence of breast cancer (see page 6, lines 15-17 of the office action of December 11, 2008). The Examiner also admits that in literature references previously provided by Applicants the term prevention of breast cancer as used in the art means to reduce the risk or

incidence of breast cancer (see page 6, lines 11-13 of the office action of December 11, 2008).

However, the Examiner then alleged that the specification "does not appear to define the scope of preventing breast cancer." Applicants respectfully disagree with this assertion. Applicants respectfully submit that the phrase "prevention of breast cancer" as used in the instant specification has its plain meaning as understood by one skilled in the art. The Examiner has admitted that the term prevention of breast cancer is understood to mean reduction of risk of or incidence of breast cancer in the literature (see page 6, lines 11-13 of the Office Action of December 11, 2008). Applicants further note that "prevention" as defined in Webster's dictionary means the act of preventing or hindering and that preventing means to keep from happening or existing (see definition attached along with IDS). Plain meaning of the phrase "prevention of breast cancer" thus means that breast cancer is kept from happening or existing which therefore means that the risk of or incidence of breast cancer is reduced. Thus, the phrase "prevention of breast cancer" as used in the instant specification has its plain meaning which is the same as that commonly used in the art as evidenced by the previously submitted literature references.

The Examiner has further alleged that the claims are broader in scope than the enabling disclosure as prevention of breast cancer is claimed but only treatment of breast cancer is provided. Applicants respectfully disagree and submit that the scope of the claims is narrow and pertains to the use of lasofoxifene for the prevention of breast cancer. The prevention of breast cancer using compounds of formula I, including lasofoxifene, is described throughout the specification, including the abstract of the invention.

The Examiner also alleges that the nature of the invention is the treatment of breast cancer comprising administering estrogen type compounds to a mammal. Applicants respectfully disagree with this assertion. The nature of the invention is the prevention of breast cancer by administering lasofoxifene which is a selective estrogen receptor modulator (SERM).

Applicants agree that the relative level of one of ordinary skill in the art is high and that Ph.Ds or M.Ds with training in medicinal chemistry, biochemistry, pharmacology or biology engage in cancer research. Applicants also agree that cancer research involves laborious, time consuming and costly experimental methods (both in vitro and in vivo). Applicants further submit that such studies are not "undue experimentation" but instead are studies recognized by those skilled in the art as required for pharmaceutical development (i.e. arriving at a therapy useful

for preventing breast cancer). Applicants agree that the prior art does not teach the prevention of breast cancer with compounds of formula I, including lasofoxifene.

With respect to the level or degree of predictability applicants agree that not all anti-cancer therapies are effective in treating all tumors. One skilled in the art readily recognizes that some experimentation is required in order to determine that a therapy works in a clinically significant fashion. Applicants have provided specific examples showing the in vivo effects of compounds of Formula I at page 19-24 of the specification.

The specification does not provide specific data on the prevention of breast cancer and the Examiner has alleged that no further evidence has been provided. Applicants respectfully disagree with this allegation. In the response filed on August 7, 2008 Applicant's submitted the following statement regarding the use of lasofoxifene for preventing breast cancer.

'"In addition, Applicants respectfully submit that the compounds of Formula I in the instant claims are useful in reducing the incidence, and thus preventing, breast cancer based upon clinical data that has been obtained.

Lasofoxifene, which is a species of within the genus of Formula I has undergone extensive clinical testing and is currently under review by the FDA for the treatment of osteoporosis. In the 5 year PEARL clinical study it was found that lasofoxifene at a 0.5 mg dose reduced the risk of ER+ (estrogen receptor positive) breast cancer by 67% through 3 years and by 81% through 5 years; reduced the risk of all breast cancer by 65% through 3 years and by 79% through 5 years; reduced the risk of ER+ invasive breast cancer by 73% through 3 years and by 85% through 5 years. Applicants respectfully submit that this data clearly shows that compounds of Formula I are useful in preventing breast cancer in humans." The decreased incidence of breast cancer in the lasofoxifene treated group compared to the control placebo group shows that the development of breast cancer has been prevented. Thus, contrary to the Examiner's allegation, Applicants respectfully submit that further evidence has been provided which shows lasofoxifene is beneficial in preventing breast cancer based on the clinical results that were obtained.

In the response filed on August 7, 2009 a declaration by David D. Thompson under 37 C.F.R. §1.132 was submitted. Applicants respectfully submit that the data submitted in the declaration shows lasofoxifene reduces the incidence of breast cancer when compared to a placebo control group and thus shows that lasofoxifene prevents breast cancer from developing as evidenced by the clinical results.

Applicants respectfully request that the Examiner carefully consider the declaration in view of the claimed subject matter. Applicants would like to further point out that the instant claims are narrow in scope and only directed to a method of preventing breast cancer with Lasofoxifene.

Issues also often arise about how much disclosure is necessary to teach one skilled in the art how to use a pharmaceutical compound in a method of treatment. In the case of In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995), the CAFC reversed a decision of the U.S. Board of Patent Appeals affirming an examiner's rejection of claims directed to 5-nitrobenzo[de]isoquinoline-1,3-dione compounds for use as antitumor agents under 35 U.S.C. § 112, paragraph 1. The examiner's initial rejection, upon which the Board relied in rendering its decision, was based specifically on a challenge to the utility of the claimed compounds and the amount of experimentation necessary to use the compounds. In his answer to the applicants' appeal brief, the examiner stated that the final rejection was based on 35 U.S.C. § 112, paragraph 1.

The CAFC pointed out that Brana taught that his compounds were antitumor agents, and that the purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles. In re Jolles, 628 F.2d at 1327, 206 U.S.P.Q. at 890. The court also noted that modern science has previously identified numerous successful chemotherapeutic agents. As such, Brana's claimed method of treating cancer was not an incredible utility and did not require undue experimentation for one skilled in the art to practice.

The facts of the instant case are in accord with the CAFC's holding in In re Brana. In the instant case, Applicants have taught how to make the compound employed in the method claim. Applicants have further shown that the compound is an estrogen agonist/antagonist and have submitted a declaration showing that the compound reduces the incidence of breast cancer in a clinical study and thus is useful in preventing breast cancer. Applicants have provided enabling disclosure of routes of administration, pharmaceutical dosage forms and dosages in the claimed methods of treatment. Applicants respectfully submit that one skilled in the art would readily be able to practice the claimed methods of treatment without undue experimentation. The CAFC, in Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 42 U.S.P.Q.2d 1001 (Fed. Cir. 1997) offered the following guidance on enablement determinations in quoting Brenner v. Manson that "a patent is not a

hunting license. It is not a reward for the search, but compensation for its successful conclusion. 383 U.S. 519, 536 (1966)." In the instant case, Applicants have successfully concluded the search for an estrogen agonist/antagonist compound which can readily be employed in the claimed method of treatment by one skilled in the art without undue experimentation. Applicants respectfully request that the Examiner reconsider the claims and in doing so interpret the terms in the claims according to their plain meaning as required. Applicants respectfully request that the Examiner reconsider in view of the references previously provided, the definition of prevention previously provided, the declaration previously provided and the remarks hereinabove and to withdraw the present rejection of claims 3 and 5-12 under 35 U.S.C. §112, first paragraph.

Applicants believe that, in view of the remarks made above that this application is in condition for allowance. Reconsideration and allowance of claims 3 and 5-12 is respectfully requested.

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